

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

WILLIAM PANZINI and EDNA PANZINI,  
Derivatively on Behalf of Nominal Defendant  
GENZYME CORPORATION,

Plaintiffs,

v.

HENRI A. TERMEER, MICHAEL S.  
WYZGA, RICHARD A. MOSCICKI,  
DOUGLAS A. BERTHIAUME, GAIL K.  
BOUDREAUZ, CONNIE MACK III,  
RICHARD F. SYRON, ROBERT J.  
CARPENTER, CHARLES L. COONEY,  
VICTOR J. DZAU, MARK R. BAMFORTH,  
ZOLTAN CSIMMA, THOMAS J.  
DESROSIER, DAVID MEEKER, ALAN E.  
SMITH, SANDFORD D. SMITH, PETER  
WIRTH, GEORGES GEMAYEL AND EARL  
M. COLLIER, JR.,

Defendants,

and

GENZYME CORPORATION,

Nominal Defendant.

Case No. \_\_\_\_\_

**VERIFIED SHAREHOLDER  
DERIVATIVE COMPLAINT**

**VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT**

Plaintiffs William Panzini and Edna Panzini (“Plaintiffs”), by the undersigned attorneys, submit this Verified Shareholder Derivative Complaint (the “Complaint”) against the defendants named herein.

**NATURE OF THE ACTION**

1. Plaintiffs bring this action derivatively for the benefit of nominal defendant Genzyme Corporation (“Genzyme” or the “Company”) against the members of Genzyme’s Board of Directors (the “Board”) and certain executive officers of the Company seeking to

remedy the Individual Defendants' (as defined herein) breaches of fiduciary duties, unjust enrichment, and statutory violations.

2. As explained herein, the Individual Defendants breached their fiduciary duties by knowingly causing the Company to: (1) falsely portray that its manufacturing facilities were compliant with FDA standards; (2) conceal the manufacturing deficiencies previously flagged by FDA inspectors; (3) conceal the true reason for the Company's inability to meet demand for its products; (4) materially mislead the Company's shareholders about the expected product and revenue growth of Cerezyme, Fabrazyme, and Myozyme; (5) materially mislead the Company's shareholders about the approval schedule of Lumizyme; (6) conceal from shareholders that the Company lacked adequate internal controls; and (7) fail to take appropriate action to prevent or correct this misconduct. Additionally, certain Individual Defendants breached their fiduciary duties to the Company and were unjustly enriched because they took advantage of their knowledge of material non-public information about Genzyme to illegally sell more than \$117 million of their personally held Genzyme stock.

3. As a direct and proximate result of the Individual Defendants' breaches of fiduciary duties, the Company has sustained damages, including, but not limited to, losses incurred in connection with lost and delayed sales of Cerezyme, Fabrazyme, Myozyme, and Lumizyme.

### **JURISDICTION**

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1331 in that this Complaint states a federal question. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. §1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

5. Venue is proper in this district because a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, occurred in this district. One or more of the defendants either resides in or maintains executive offices in this district, and defendants have received substantial compensation in this district by engaging in numerous activities and conducting business here, which had an effect in this district.

### **PARTIES**

6. Plaintiffs are shareholders of nominal defendant Genzyme, were shareholders of Genzyme at the time of the wrongdoing alleged herein, and have been shareholders of Genzyme continuously since that time. Plaintiffs are citizens of the Commonwealth of Massachusetts.

7. Nominal defendant Genzyme is a Massachusetts corporation with its principal executive offices located at 500 Kendall Street, Cambridge, Massachusetts 02142. According to its public filings, Genzyme is one of the world's leading biotechnology companies, a leader in the effort to develop and apply the most advanced technologies in the life sciences, with many established products and services helping patients with rare inherited genetic disorders in nearly 100 countries. Genzyme's common stock is traded on the NASDAQ stock exchange under the symbol "GENZ".

8. Defendant Henri A. Termeer ("Termeer") has served as the President, Chief Executive Officer ("CEO") and Chairman of the Board since 1983, 1985 and 1988, respectively. Defendant Termeer is a citizen of the Commonwealth of Massachusetts.

9. Defendant Michael S. Wyzga ("Wyzga") has served as Chief Financial Officer ("CFO") since July 1999 and Executive Vice President, Finance since May 2003. Defendant Wyzga is a citizen of the Commonwealth of Massachusetts.

10. Defendant Richard A. Moscicki (“Moscicki”) has served as Chief Medical Officer since September 1996 and Senior Vice President, Biomedical & Regulatory Affairs since May 2008. Defendant Moscicki is a citizen of the Commonwealth of Massachusetts.

11. Defendant Douglas A. Berthiaume (“Berthiaume”) has served as a director of the Company since 1988 and has been a member of the Audit Committee of the Board (the “Audit Committee”) since at least 2006. Defendant Berthiaume is a citizen of the Commonwealth of Massachusetts.

12. Defendant Gail K. Boudreaux (“Boudreaux”) has served as a director of the Company since 2004 and has been a member of the Audit Committee since at least 2006. Defendant Boudreaux is a citizen of the State of Illinois.

13. Defendant Connie Mack III (“Mack”) has served as a director of the Company since 2001 and has been a member of the Audit Committee since at least 2006. Defendant Mack is a citizen of the State of Florida.

14. Defendant Richard F. Syron (“Syron”) has served as a director of the Company since 2006 and has been a member of the Audit Committee since at least 2006. Defendant Syron is a citizen of the Commonwealth of Massachusetts.

15. Defendant Robert J. Carpenter (“Carpenter”) has served as a director of the Company since 1994. Defendant Carpenter is a citizen of the Commonwealth of Massachusetts.

16. Defendant Charles L. Cooney (“Cooney”) has served as a director of the Company since 1983. Defendant Cooney is a citizen of the Commonwealth of Massachusetts.

17. Defendant Victor J. Dzau (“Dzau”) has served as a director of the Company since 2000. He is also the chancellor for health affairs at Duke University and president and CEO of the Duke University Health System. Defendant Dzau is a citizen of the State of North Carolina.

18. Defendant Peter Wirth (“Wirth”) is Genzyme’s Executive Vice President, Legal and Corporate Development and Secretary. He joined the Company in 1996. Defendant Wirth is a citizen of the Commonwealth of Massachusetts.

19. Defendant Earl M. Collier, Jr. (“Collier”) has served as Genzyme’s Executive Vice President, Genetics since January 2007 and Executive Vice President, Cardiovascular and Oncology since August 2003. Defendant Collier is a citizen of the Commonwealth of Massachusetts.

20. Defendant Alan E. Smith (“A. Smith”) is Genzyme’s Senior Vice President, Research and Chief Scientific Officer. He joined the Company in 1989. Defendant A. Smith is a citizen of the Commonwealth of Massachusetts.

21. Defendant Sanford D. Smith (“S. Smith”) is Genzyme’s Executive Vice President and President of the International Group. He joined the Company in 1996. Defendant S. Smith is a citizen of the Commonwealth of Massachusetts.

22. Defendant Georges Gemayel (“Gemayel”) served as Genzyme’s Executive Vice President, Therapeutics and Biosurgery from 2003 to May 2008. Defendant Gemayel is a citizen of the Commonwealth of Massachusetts.

23. Defendant Mark R. Bamforth (“Bamforth”) is Genzyme’s Senior Vice President, Corporate Operations and Pharmaceuticals. He joined the Company in 1988. Defendant Bamforth is a citizen of the Commonwealth of Massachusetts.

24. Defendant David Meeker (“Meeker”) is Genzyme’s Executive Vice President, Therapeutics, Biosurgery & Corporate Operations. He joined the Company in 1994. Defendant Meeker is a citizen of the Commonwealth of Massachusetts.

25. Defendant Thomas J. DesRosier (“DesRosier”) is Genzyme’s Senior Vice President, General Counsel and Chief Legal Officer. He joined the Company in 1999. Defendant DeRosier is a citizen of the Commonwealth of Massachusetts.

26. Defendant Zoltan Csimma (“Csimma”) is Genzyme’s Senior Vice President, Chief Human Resources. He joined the Company in 2000. Defendant Csimma is a citizen of the Commonwealth of Massachusetts.

27. Collectively, defendants Wirth, Collier, A. Smith, S. Smith, Gemayal, Bamforth, Meeker, Mack, DeRosier and Csimma are referred to herein as the “Insider Sales Defendants.”

28. Collectively, defendants Termeer, Berthiaume, Boudreaux, Mack, Syron, Carpenter, Cooney and Dzau are referred to herein as the “Director Defendants.”

29. Collectively, defendants Termeer, Wyzga, Moscicki, Berthiaume, Boudreaux, Mack, Syron, Carpenter, Cooney, Dzau, Wirth, Collier, A. Smith, S. Smith, Gemayal, Bamforth, Meeker, DeRosier and Csimma are referred to herein as the “Individual Defendants.”

#### **DUTIES OF THE INDIVIDUAL DEFENDANTS**

30. By reason of their positions as officers and/or directors of the Company and because of their ability to control the business and corporate affairs of the Company, the Individual Defendants owed the Company and its shareholders the fiduciary obligations of good faith, trust, loyalty, and due care, and were and are required to use their utmost ability to control and manage the Company in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of the Company and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to the Company and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the

affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

31. The Individual Defendants, because of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

32. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

- a. exercise good faith in ensuring that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business;
- b. exercise good faith in ensuring that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, including acting only within the scope of its legal authority;
- c. exercise good faith in ensuring that the Company's financial statements were prepared in accordance with GAAP;
- d. exercise good faith in supervising the preparation and filing of all financial statements, press releases, audits, reports or other information required by law, and in examining and evaluating any reports or examinations, audits, or other information concerning the financial affairs of the Company; and
- e. when placed on notice of improper or imprudent conduct by the Company and/or its employees, exercise good faith in taking action to correct the misconduct and prevent its recurrence.

33. The Individual Defendants, particularly defendants Berthiaume, Boudreaux, Mack, and Syron as members of the Audit Committee, were responsible for maintaining and establishing adequate internal accounting controls for the Company, and ensuring that the Company's financial statements were based on accurate financial information. According to

GAAP and SEC rules, to accomplish the objectives of accurately recording, processing, summarizing, and reporting financial data, a corporation must establish an internal accounting control structure. Among other things, the Individual Defendants were required to:

- a. make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer; and
- b. devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –
  - i. transactions are executed in accordance with management's general or specific authorization; and
  - ii. transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP.

34. According to the Audit Committee's Charter, the Audit Committee's purpose is to "provide assistance to the full Board of Directors of the Corporation in fulfilling its responsibility to the shareholders, potential shareholders and investment community relating to the accounting and financial reporting practices of the Corporation, and the quality and integrity of the financial reports of the Corporation." In this respect, the Audit Committee's primary oversight duties include the following:

- Oversee that management has maintained the reliability and integrity of the accounting policies, independent audit process and financial reporting and disclosure practices of the Corporation;
- Oversee that management has established and maintained processes to assure that an adequate system of internal controls is functioning within the Corporation; and
- Oversee that management has established and maintained processes to assure compliance by the Corporation with all applicable laws, regulations and corporate policy.

35. In fulfillment of these duties, the Audit Committee Charter provides that the Audit Committee shall, among other things:



### Reports and Review

- Review with the Corporation's management and the independent Auditors the interim financial statements of the Corporation prior to their filing or prior to the release of earnings, including a discussion with the independent Auditors of the matters to be discussed under Statement of Auditing Standards ("SAS") No. 61, as amended, which include:
  - The Corporation's significant accounting policies;
  - Management judgments and accounting estimates; and
  - Other information in documents containing audited financial statements.
- Review with the independent Auditors at the completion of the annual examination the independent Auditors' judgments about the quality, not just the acceptability, of the corporation's accounting principles as applied in its financial reporting. The review should include a discussion of:
  - The consistency of application of the Corporation's accounting policies and the clarity, consistency and completeness of the Corporation's accounting information contained in its financial statements and related disclosures; and
  - Items that have a significant impact on the representational faithfulness, verifiability, neutrality and consistency of the accounting information included in the Corporation's financial statements.

### Financial Reporting Process

- Prior to the filing of the Corporation's Annual Report on Form 10-K and each Quarterly Report on Form 10-Q, discuss with management and the Independent Auditors the quality and adequacy of the Corporation's internal controls, including any significant deficiencies in the design or operation of these controls which could adversely affect the Corporation's ability to record, process, summarize, and report financial data.
- Prior to the filing of the Corporation's Annual Report on Form 10-K and each Quarterly Report on Form 10-Q, discuss with management and the Independent Auditors any fraud, whether or not material, that involves management or other employees who have a significant role in the Corporation's internal controls.
- Consider and approve, if appropriate, significant changes to the Corporation's accounting principles and practices proposed by management. Discuss with the Corporation's Independent Auditors any significant changes in auditing standards or their scope.

- Establish regular systems of reporting to the Audit Committee by the Corporation's management and the Corporation's Independent Auditors regarding significant judgments made in management's preparation of the Corporation's financial statements and significant difficulties encountered during the course of the review or audit, including restrictions in the scope of work or access to required information.

#### Legal Compliance/General

- Review with the Corporation's legal advisors legal matters that could have a significant impact on the Corporation's financial statements.
- Report material information through its Chairperson to the Board following meetings of the Audit Committee.
- Engage independent counsel and other advisors, as the Audit Committee determines necessary to carry out its duties.

### **FACTUAL ALLEGATIONS**

#### **Background on Genzyme**

36. Genzyme was founded in 1981 and has since grown into one of the leading biotechnology firms in the world. The Company has more than 11,000 employees and generated \$4.6 billion in revenues in 2008. Genzyme products and services, which are geared toward the treatment of rare inherited disorders, kidney disease, orthopedics, transplant and immune disease, and diagnostic testing, are sold to patients in approximately 100 countries.

37. Genzyme produces a number of products that are "biologics" as opposed to traditional pharmaceuticals that are chemically synthesized. Biologics are produced from natural sources using special technologies and biotechnological methods. Furthermore, biologics are often heat sensitive and susceptible to microbial contamination. As a result, aseptic principles must be adhered to from the initial steps of their production.

38. This lawsuit concerns manufacturing and contamination problems involving several of Genzyme's biologics that were manufactured at the Company's facility located in Allston, Massachusetts (the "Allston Facility"). The biologics discussed herein are Myozyme,

also known as Lumizyme when produced in a new formulation (explained below), Cerezyme and Fabrazyme.

39. Myozyme is the only available treatment for Pompe disease, a rare genetic disorder in which patients are missing an enzyme to break down glycogen, which builds up in certain tissues like the heart and muscles and can lead to breathing difficulties, heart problems and muscle weakness. When Pompe disease is diagnosed at a young age, it can progress very quickly and will likely be fatal without any treatment. Therefore, treating infants and children with Pompe is a top priority.

40. In April 2006, Genzyme received FDA approval to sell Myozyme produced at the 160 L scale (“160 L Myozyme”) in the United States. At that time, Genzyme also began producing Myozyme at the 2000 L (“2000 L Myozyme”) scale for the international market. Shortly thereafter, Genzyme sought the FDA’s approval to sell 2000 L Myozyme in the United States market. In doing so, Genzyme renamed the 2000 L Myozyme formulation as Lumizyme for distribution in the United States.

41. Cerezyme is Genzyme’s highest revenue generating product. In 2008, Cerezyme generated \$1.2 billion in revenues for the Company. Cerezyme is an enzyme replacement therapy specifically used for the treatment of Gaucher disease, which causes fatty material to collect in the spleen, liver, kidneys, lungs, brain and bone marrow. Gaucher disease often causes liver malfunction, anemia and severe neurological complications.

42. Fabrazyme is the Company’s third highest revenue generating product. In 2008, Fabrazyme generated nearly \$500 million in revenue for Genzyme. Fabrazyme is used to treat Fabry disease, a condition caused by enzymes that are needed to metabolize lipids and other fat-

like substances. Fabry disease leads a build up of harmful levels of lipids in the eyes, kidneys, nervous system and cardiovascular system.

### **Individual Defendants' Breaches of Their Fiduciary Duties**

43. In July 2007, Genzyme began to inform its shareholders about the FDA's approval of Lumizyme. The FDA's approval, which would allow for the large scale manufacturing of Lumizyme in the United States, was critical for the Company to meet its 2008 earnings guidance and projections. While manufacturing challenges with Lumizyme were indentified in Genzyme's earnings release, the Company nevertheless continued to assure shareholders that the challenges would be overcome and assumed the approval of Lumizyme in its guidance for 2008.

44. On July 25, 2007, the Individual Defendants caused Genzyme to issue a press release disclosing its financial results for the quarter ended June 30, 2007 (the "July 25, 2007 Press Release"). With regard to the FDA's approval of Lumizyme, the July 25, 2007 Press Release stated the following:

Sales of Genzyme's four treatments for lysosomal storage disorders showed continued strength in the second quarter, driven by the growing number of patients receiving therapy. Sales of Myozyme® (alglucosidase alfa) rose to \$46.7 million, compared with \$6.5 million in the same period a year ago following product launch. Last month, Genzyme launched Myozyme in Japan, and the company is preparing for approval in Brazil, another key market. **Genzyme is pursuing FDA approval of a larger scale manufacturing process to supply Myozyme for the U.S. market, and an agency decision is now expected in the first half of next year. Production at this larger scale is already approved in 28 countries. The company is accelerating efforts to optimize product supply for the U.S. market until the FDA approves the larger-scale process.** These efforts include temporarily transitioning some patients to a clinical access program through which they may receive Myozyme produced at the larger scale. The study of Myozyme involving patients with late-onset Pompe disease will conclude this year, and results will be available in the first part of next year for submission to regulatory authorities.

(Emphasis added)

45. On the same day, during a conference call regarding the Company's earnings for the quarter ended June 30, 2007, Defendant Termeer responded to an analyst's question regarding the FDA approval of Lumizyme. In doing so, Defendant Termeer reiterated the Company's position, virtually guaranteeing that it would receive FDA approval to market Lumizyme in the United States in the first half of 2008: "We will **no doubt**, when this situation is controlled in the first half of next year, **when the FDA has made the decision to approve the large scale [Lumizyme] as 28 other countries have already done**, you will see a bit of a step function as these patients convert to commercial drug." (Emphasis added). As it would later become clear, the foregoing statements were false and misleading when made because the manufacturing issues and challenges that the Company faced were far more severe than the Company publicly acknowledged, thus substantially jeopardizing the likelihood of FDA approval of Lumizyme.

46. On April 10, 2008, the Director Defendants caused the Company to issue a false and misleading Form 14A (the "2008 Proxy Statement"). The 2008 Proxy asked shareholders to vote on the following relevant matters:

- The re-election of five directors, each for a one-year term;
- An amendment to Genzyme's 2004 Equity Incentive Plan to increase the number of shares of common stock covered by the plan by 2,250,000 shares; and
- An amendment to Genzyme's 2007 Director Equity Plan to specify the automatic grant provisions under the plan.

47. The 2008 Proxy Statement was false and misleading because it failed to disclose material information regarding Genzyme's manufacturing problems and their impact on the Company that would affect the shareholder votes on the matters listed above.

48. On April 23, 2008, the Individual Defendants caused Genzyme to issue a press release disclosing its financial results for the quarter ended March 31, 2008 (the “April 23, 2008 Press Release”). In the April 23, 2008 Press Release, as the Individual Defendants had anticipated but knowingly failed to disclose to shareholders, the Company reported that it had failed to obtain FDA approval for Lumizyme. Instead, the FDA informed Genzyme that it would require the 2000 L Myozyme (to be named Lumizyme upon approval) to be submitted to independent trials because the Company’s manufacturing of 2000 L Myozyme yielded enzymes with different characteristics than the smaller 160 L Myozyme formulation. Nevertheless, the Company still assured shareholders that approval would be received by the end of 2008. In relevant part, the April 23, 2008 Press Release stated the following:

Within the Therapeutics business, worldwide demand for Myozyme remains robust two years into the product’s launch. First-quarter sales rose 78 percent despite the delay in U.S. approval for 2000L production capacity. Sales increased to \$67.3 million from \$37.9 million in the period a year ago, driven by the number of new patients starting therapy. As announced, the FDA will require Genzyme to submit a BLA [biologics license application] to obtain U.S. commercial approval for Myozyme produced at the 2000L scale. The agency is expected to act on the application by the end of this year.

49. Although not disclosed to shareholders until six months later, in September 2008, the FDA inspected several of Genzyme’s production facilities, including the Allston Facility, and provided the Company with a list of practices that deviated from the FDA’s Good Manufacturing Practice (“GMP”) standards. The Individual Defendants did not publicly disclose the FDA’s inspection or any of the problems that the FDA detailed to the Company in its inspection report, despite knowing that the FDA would not approve Lumizyme until all of the manufacturing problems were corrected by the Company.

50. Genzyme also experienced instances of contamination at its manufacturing plants in the fall of 2008, including at the Allston Facility. Like the FDA’s findings of Genzyme’s

GMP deviations, these instances of contamination were not disclosed to the Company's shareholders, even though these issues affected Genzyme's ability to meet consumer demand for Myozyme. This would subsequently lead to a supply shortage of the product in the marketplace to the extent that the Company would be forced to ration its distribution.

51. On February 27, 2009, Genzyme received two letters from the FDA. The first, which was titled "Warning Letter" and was addressed to Defendant Termeer, conveyed the FDA's continuing concerns regarding GMP compliance at the Company's Allston Facility. In the second letter, the FDA indicated that it would not approve Lumizyme by the expected February 28 deadline and would withhold approval until the issues identified regarding the Allston Facility were resolved.

52. Finally, in its Form 10-K filed on March 2, 2009 (the "2008 10-K"), the Individual Defendants caused Genzyme to disclose the FDA's findings and its concerns about the Company's deficient GMP standards. In relevant part, the 2008 10-K stated the following:

In September and October 2008, FDA officials conducted a Good Manufacturing Practices, or GMP, inspection of licensed therapeutic drug products, bulk drug substances and drug components manufactured at our Allston, Massachusetts facility. We manufacture Cerezyme, Fabrazyme and Myozyme and perform fill/finish for Aldurazyme and Thyrogen at this facility. After this inspection, the FDA officials issued a list of inspection observations known as a Form FDA 483. The form detailed inspectional observations considered by the FDA to be significant deviations from GMP compliance, including observations relating to our procedures designed to prevent microbiological contamination of sterile drug products; controls for in-process monitoring during bulk drug substance manufacturing, including our controls for bioburden monitoring; and maintenance of equipment and computer systems validation. We responded to the Form FDA 483 on October 31, 2008 with a plan and timeline to address the inspectional observations and provided a progress update on February 23, 2009 to the FDA. On February 27, 2009, we received a warning letter from the FDA that requested supplemental information in order to fully evaluate the adequacy of our corrective actions with respect to nine of the FDA's sixteen observations in the Form FDA 483. We currently are reviewing the warning letter and plan to respond to the FDA in writing within fifteen business days of receipt of the letter as is required. We are committed to working cooperatively with the FDA regarding this matter.

The issuance of the warning letter does not affect the continued distribution of our Genetic Diseases products currently on the market or our inventory currently on hand. We believe that the products produced at our Allston facility continue to meet the highest quality and safety standards.

Failure to correct the deviations cited in the FDA's warning letter could result in further regulatory action, including suspension of our license to manufacture products at the facility, or lead to a delay in the approval of new products. The FDA will not approve our application to market alglucosidase alfa produced at the 2000L scale [Lumizyme] at our Allston facility until the issues identified in the warning letter are resolved to the FDA's satisfaction.

53. Thus, approximately six months **after** being notified by the FDA of the problems at the Allston Facility, Genzyme belatedly disclosed these issues, as well as the fact that the FDA would not approve Lumizyme until after the FDA's concerns were fully addressed. In response to the announcement, on March 3, 2009, Genzyme's stock closed at \$52.48 after having dropped 7.7%, or \$4.04 per share, from its closing price of \$56.52 on March 2, 2009.

54. On March 11, 2009, *The Wall Street Journal* published an article entitled, "FDA Warns Genzyme on Plant Conditions" (the "March 11, 2009 WSJ Article"). The March 11, 2009 WSJ Article provided excerpts of a redacted copy of the FDA's February 27, 2009 "Warning Letter" which the newspaper received from the FDA. In relevant part, the March 11, 2009 WSJ Article stated the following:

U.S. Food and Drug Administration investigators found "significant objectionable conditions" during an inspection of a Genzyme Corp. plant [the Allston Facility] that makes expensive biotechnology drugs, according to a copy of an agency warning letter.

The Feb. 27 letter outlines a number of deficiencies in the manufacturing process at the Boston plant [the Allston Facility], which produces some of the company's best-selling products, including drugs such as Myozyme, Cerezyme and Fabrazyme.

FDA investigators inspected the plant from Sept. 15 through Oct. 10 and "documented significant deviations from current good manufacturing practice."



The problems fall into four areas involving maintenance of equipment, computerized systems, production controls and the failure to follow procedures aimed at preventing microbiological contamination.

Much of the six-page letter involves highly technical critiques of the manufacturing process.

“The deficiencies described in this letter are indicative of your quality control unit’s failure to fulfill its responsibility to assure the identity, strength, quality and purity of your drug products and drug substances,” the letter says.

For instance, the FDA said Genzyme failed to perform maintenance on large aluminum freezers used to transport cell banks and was using freezers – called cryoshippers – beyond their stated life expectancy. Mr. Bamforth says the company has changed its procedures following the inspection.

55. The March 11, 2009 WSJ Article also included statements made by defendant Bamforth. In relevant part, the March 11, 2009 WSJ article stated that:

Mark Bamforth said the company has addressed about 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April. He said the company met with FDA officials on March 6 to review the outstanding issues. Mr. Bamforth said the FDA indicated it planned to re-inspect the plant once Genzyme indicates it has taken all of the corrective action. He said the Boston plant continues to produce treatments and that “the efficacy and safety of our products is unchanged.”

56. On March 11, 2009, Genzyme’s stock dropped 4.3%, or \$2.37 per share, to close at \$52.82. At this point, the contamination problems at the Allston Facility in the Fall of 2008 had still not been publicly disclosed.

57. On April 13, 2009, the Director Defendants caused the Company to issue a false and misleading Form 14A (the “2009 Proxy Statement”). The 2009 Proxy asked shareholders to vote on the following relevant matters:

- The re-election of eight directors, each for a one-year term;
- An amendment to Genzyme’s 2004 Equity Incentive Plan to increase the number of shares of common stock available for issuance under the plan by 2,500,000 shares; and
- Approval of the 2009 Employee Stock Purchase Plan.

58. The 2009 Proxy Statement was false and misleading because it failed to disclose material information regarding Genzyme's manufacturing problems and their impact on the Company that would affect the shareholder votes on the matters listed above.

59. On April 22, 2009, the Individual Defendants caused Genzyme to issue a press release disclosing its financial results for the quarter ended March 31, 2009 (the "April 22, 2009 Press Release"). The Company reported financial results that were below analysts' expectations. In part, the Company attributed its inability to meet analysts' expectations to supply constraints, stating that: "[r]evenue reflects the company's inability to sell the product [Myozyme] for use by late-onset Pompe patients in the United States, and a global supply management program under which adults with Pompe disease temporarily missed doses in order to preserve constrained supply for infants and children." Notably, what the Company failed to disclose was that the supply constraints resulted from the contamination and manufacturing issues that arose in the Fall of 2008, but had still not been disclosed. Genzyme nevertheless reaffirmed its revenue and earnings guidance for 2009 and informed investors that it anticipated the approval of Lumizyme "late in the second quarter or in the third quarter" of 2009.

60. On June 16, 2009, the Individual Defendants caused Genzyme to issue a press release disclosing that the Company had detected a virus that would further impede production of its biologics at the Allston Facility (the "June 16, 2009 Press Release"). Consequently, in the June 16, 2009 Press Release, the Company also announced that it would have to suspend production of Cerezyme and Fabrazyme, two of the Company's top-selling drugs which were manufactured at the Allston Facility, in order to sanitize the entire facility. Additionally, the Company disclosed for the first time that the virus that was just detected was the same virus that had caused the decline in productivity at the Allston Facility in the fall of 2008. That is, the

same virus that had caused shortages of Myozyme in the first quarter of 2009 was now causing shortages of Cerezyme and Fabrazyme.

61. Genzyme's stock dropped 5.5%, or \$3 per share, from its \$55.62 close on June 15, 2009 to its close at \$52.75 on June 15, 2009.

62. The Allston Facility remained closed for the months of June and July of 2009, and the Company was forced to ration Cerezyme and Fabrazyme to the marketplace due to their high demand and the Company's low inventory of the products.

63. On July 22, 2009, the Individual Defendants caused Genzyme to issue a press release (the "July 22, 2009 Press Release") lowering its earnings forecast for 2009 from \$3.52 per share to a range of \$2.35 to \$2.90 per share. The July 22, 2009 Press Release stated that the shutdown of the Allston Facility had caused the Company a \$13 million loss of revenue for the quarter ended June 30, 2009. Due to the product shortages caused by the shutdown, Genzyme lowered its 2009 revenue projections for: a) Cerezyme to a range of \$750 million to \$1 billion from a prior forecast of \$1.25 billion to \$1.275 billion, b) Myozyme to a range of \$330 million to \$340 million from a previous range of \$370 million to \$380 million, and c) Fabrazyme to a range of \$510 million to \$520 million from a prior forecast of \$560 million to \$570 million. In sum, Genzyme reduced its 2009 revenue projections to between \$4.6 billion and \$5 billion, down from a previous estimate of \$5.15 billion to \$5.35 billion.

64. In response to the lowered forecast, Genzyme's stock dropped 8.4%, or \$4.70 per share, from its \$55.91 close on July 21, 2009 to close at \$51.21 on July 22, 2009.

65. In a Form 10-Q filed on August 10, 2009 (the "August 10, 2009 10-Q"), Genzyme reported that the FDA needed to re-inspect the Company's Allston Facility another time, as at the time of the FDA's inspection in May 2009 the Company had failed to address all

of the problems that the FDA had previously highlighted. Genzyme also stated that the FDA was going to examine all of the steps that the Company took to sterilize its equipment during the shutdown of the Allston Facility. In relevant part, the August 10, 2009 10-Q stated the following:

...the FDA's CR Letter stated that before the FDA would approve Lumizyme, we would need to resolve issues identified in a Warning Letter related to our Allston facility that we received in February 2009, on the same day as the CR Letter. An FDA inspector inspected the plant in May 2009 as a follow up to the Warning Letter. At the end of July 2009, the FDA informed us that it will re-inspect our Allston facility to verify that all corrective and preventative actions identified in the February Warning Letter have been implemented. The FDA indicated that all promised actions had not been either fully or adequately implemented at the time of the May inspection, such as identifying measures to prevent column rouging; inspection and preventative maintenance, or PM, of remaining chromatography columns; revision of PM scheduled inspection to every six months for Chromaflow columns and an annual inspection for all other column types; revision of column packing records to include internal inspection; development of on the job training for preventative maintenance and division of maintenance responsibility; and implementation of the revised transfer/transport procedures for cryoshippers. In addition, recent remediation of the Allston facility in response to the Vesivirus 2117 contamination employed cleaning procedures using sodium hypochlorite and vaporized hydrogen peroxide treatment of columns. The cleaning validation will be reviewed during the next inspection along with our investigation and other remediation efforts related to the identification of the virus at our Allston facility. We will work with the FDA to schedule the re-inspection as soon as possible.

66. The August 10, 2009 10-Q also disclosed that Genzyme was forced to dispose of at least 80% of the ingredients and in-process materials for Cerezyme, and as a result, the Company had recorded an \$8.4 million pre-tax charge for the loss of materials. Furthermore, Genzyme stated that it did not expect new supply of the drug to be available until November 2009. In relevant part, the August 10, 2009 10-Q stated the following:

[the Company] decided not to process approximately 80% of the Cerezyme work-in-process material that was in inventory when we temporarily suspended production at our Allston facility on June 16, 2009. As a result, we have recorded \$8.4 million as a pre-tax charge to cost of products sold in our consolidated statement of operations for the three and six months ended June 30, 2009 and a

reduction to inventories in our consolidated balance sheet as of June 30, 2009 to write off this material[.]

67. The following day, on August 11, 2009, the Individual Defendants caused Genzyme to issue a press release (the “August 11, 2009 Press Release”) which also discussed the disposal of the Cerezyme ingredients and in-process materials that had to be discarded. The Company disclosed that it may have to dispose of up to 100% of the Cerezyme ingredients and in-process materials as well as two lots of Cerezyme that were completed before the Allston Facility was closed. In relevant part, the August 11, 2009 Press Release stated that:

The company continues to evaluate whether to finish the remaining work-in-process material. If Genzyme does not finish and release any of the remaining material, the company would incur an additional write-off of approximately \$2.7 million. In addition, Genzyme is currently in discussions with regulatory authorities regarding the release of two lots of Cerezyme that were finished before the plant was shut down. If these finished goods are not released, Genzyme will incur an additional write-off of \$3.1 million.

68. On September 1, 2009, in an article entitled “Inspectors Find Major Flaws at Genzyme Plant,” *The Boston Globe* reported that the European Medicines Agency had recently inspected the Allston Facility and identified a “major deficiency” at the plant. This prompted one analyst to downgrade Genzyme’s stock, and even go so far as to state that “While we have urged patience until now, we are surprised that there are still significant deviations at Allston this late in the game.” The analyst also reported that fewer than 10% of European Medicines Agency observations have been characterized as “major,” and lowered his Cerezyme estimates “considerably” through 2012 as he felt “that the odds of continued delays at Allston Landing and longer-lasting fallout of said delays are now higher.”

#### **The Insider Sales Defendants’ Illegal Insider Stock Sales**

69. Based on their knowledge of material non-public information regarding the contamination and manufacturing issues at the Allston Facility, as well as the other adverse facts

described above, from, July 25, 2007 to August 11, 2009, defendants Wirth, Collier, A. Smith, S. Smith, Gemayal, Bamforth, Meeker, Mack, DeRosier and Csimma illegally sold more than \$117 million worth of their personally held Genzyme stock at artificially high prices, as follows:

Name	Date of Sale	# Shares Sold	Price per Share	Gross Proceeds
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Henri A. Termeer	5/26/2009	9,637	\$56.54	\$544,849.00
	12/7/2007	20,000	\$72.40	\$1,448,000.00
	10/30/2007	50,723	\$73.56	\$3,731,183.88
	10/29/2007	32,241	\$75.06	\$2,420,009.46
	10/29/2007	5,500	\$74.00	\$407,000.00
	10/29/2007	120,285	\$73.53	\$8,844,556.05
	10/26/2007	257,053	\$75.07	\$19,296,968.71
	<b>Total:</b>	<b>495,439</b>		<b>\$36,692,567.10</b>

Peter Wirth	1/16/2009	232,180	\$66.50	\$15,439,970.00
	<b>Total:</b>	<b>232,180</b>		<b>\$15,439,970.00</b>

Richard A. Moscicki	9/23/2008	36,635	\$76.73	\$2,811,003.55
	6/25/2008	36,635	\$72.00	\$2,637,720.00
	1/17/2008	45,793	\$82.00	\$3,755,026.00
	1/8/2008	45,793	\$78.00	\$3,571,854.00
	12/31/2007	21,334	\$74.68	\$1,593,223.12
	<b>Total:</b>	<b>186,190</b>		<b>\$14,368,826.67</b>

Earl M. Collier, Jr.	5/26/2009	1,641	\$56.54	\$92,779.68
	7/8/2008	16,200	\$75.00	\$1,215,000.00
	1/16/2008	90,000	\$80.00	\$7,200,000.00
	10/15/2007	32,400	\$75.00	\$2,430,000.00
	<b>Total:</b>	<b>141,011</b>		<b>\$10,937,779.68</b>

Alan E. Smith	6/2/2009	1,809	\$61.40	\$111,064.82
	5/26/2009	885	\$56.54	\$50,036.31
	12/8/2008	55,521	\$65.17	\$3,618,303.57
	8/14/2008	15,000	\$82.51	\$1,237,650.00
	8/5/2008	27,761	\$78.00	\$2,165,358.00
	7/15/2008	18,455	\$79.70	\$1,470,863.50
	12/17/2007	20,000	\$75.00	\$1,500,000.00
	<b>Total:</b>	<b>140,121</b>		<b>\$10,153,276.20</b>

Sandford D. Smith	5/26/2009	1,641	\$56.54	\$92,785.91
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	1/16/2008	20,181	\$79.70	\$1,608,425.70
	1/11/2008	4,719	\$79.70	\$376,104.30
	1/9/2008	100	\$79.70	\$7,970.00
	10/15/2007	25,000	\$74.77	\$1,869,250.00
	10/10/2007	25,000	\$69.80	\$1,745,000.00
	<b>Total:</b>	<b>76,641</b>		<b>\$5,699,535.91</b>

Robert J. Carpenter	5/22/2009	1,000	\$58.70	\$58,700.60
	5/15/2009	1,452	\$59.40	\$86,243.86
	5/14/2009	10,000	\$60.33	\$603,277.00
	5/13/2009	10,000	\$60.62	\$606,238.00
	5/12/2009	2,548	\$60.70	\$154,652.64
	5/12/2009	7,452	\$60.70	\$452,304.36
	5/11/2009	10,000	\$61.28	\$612,775.00
	11/15/2007	18,543	\$73.05	\$1,354,566.15
	11/2/2007	1,219	\$75.00	\$91,425.00
	11/1/2007	17,324	\$75.00	\$1,299,300.00
	<b>Total:</b>	<b>79,538</b>		<b>\$5,319,482.61</b>

Charles L. Cooney	6/1/2009	2,500	\$59.40	\$148,508.75
	5/13/2009	3,000	\$60.19	\$180,570.00
	4/24/2009	4,000	\$53.35	\$213,386.40
	2/23/2009	6,000	\$69.69	\$418,140.00
	5/2/2008	27,000	\$70.67	\$1,908,090.00
	<b>Total:</b>	<b>42,500</b>		<b>\$2,868,695.15</b>

Georges Gemayel	10/30/2007	37,500	\$76.00	\$2,850,000.00
	<b>Total:</b>	<b>37,500</b>		<b>\$2,850,000.00</b>

Michael S. Wyzga	8/12/2008	29,390	\$79.00	\$2,321,810.00
	12/17/2007	5,140	\$74.89	\$384,934.60
	<b>Total:</b>	<b>34,530</b>		<b>\$2,706,744.60</b>

Mark R. Bamforth	8/14/2009	19,232	\$81.71	\$1,571,446.72
	8/6/2008	6,445	\$79.00	\$509,155.00
	7/15/2008	6,445	\$79.00	\$509,155.00
	<b>Total:</b>	<b>32,122</b>		<b>\$2,589,756.72</b>

Douglas A. Berthiaume	11/4/2008	11,200	\$74.59	\$835,408.00
	5/21/2008	24,000	\$67.71	\$1,625,040.00
	<b>Total:</b>	<b>35,200</b>		<b>\$2,460,448.00</b>

Victor J. Dzau	11/29/2007	5,000	\$75.00	\$375,000.00
	11/21/2007	10,000	\$72.00	\$720,000.00
	11/13/2007	10,000	\$72.00	\$720,000.00

	<b>Total:</b>	<b>25,000</b>		<b>\$1,815,000.00</b>
David Meeker	8/15/2008	17,790	\$83.19	\$1,479,950.10
	<b>Total:</b>	<b>17,790</b>		<b>\$1,479,950.10</b>
Connie Mack III	3/3/2008	19,900	\$72.32	\$1,439,168.00
	<b>Total:</b>	<b>19,900</b>		<b>\$1,439,168.00</b>
Thomas DesRosier	8/7/2008	10,725	\$78.99	\$847,167.75
	<b>Total:</b>	<b>10,725</b>		<b>\$847,167.75</b>
Zoltan Csimma	5/26/2009	638	\$56.54	\$36,069.46
	<b>Total:</b>	<b>638</b>		<b>\$36,069.46</b>

70. As a result of the sales detailed above, the Insider Sales Defendants were unjustly enriched and the proceeds from these sales should be returned to the Company.

#### **DERIVATIVE AND DEMAND ALLEGATIONS**

71. Plaintiffs bring this action derivatively in the right and for the benefit of Genzyme to redress the Individual Defendants' breaches of their fiduciary duties. Plaintiffs are owners of Genzyme stock and were owners of Genzyme stock at all times relevant hereto. Plaintiffs will adequately and fairly represent the interests of Genzyme and its shareholders in enforcing and prosecuting its rights.

72. On September 17, 2009, Plaintiffs made a demand (the "Demand") on the Board, as required by G.L. c. 156D, § 7.42. A copy of the Demand is attached hereto as Exhibit A. As of the filing of this Complaint, the Board has not taken action as demanded.

#### **COUNT I**

#### **AGAINST THE DIRECTOR DEFENDANTS FOR VIOLATIONS OF §14(a) OF THE SECURITIES EXCHANGE ACT**

73. Plaintiffs incorporate by reference all preceding and subsequent paragraphs as if fully set forth herein.



74. Rule 14-A-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. §240.14-A-9.

75. The 2008 and 2009 Proxy Statements described herein violated §14(a) and Rule 14-A-9 because the Director Defendants omitted material facts regarding the contamination and manufacturing issues at the Allston Facility, facts which the Director Defendants were aware of since at least July of 2007.

76. The Director Defendants knew that the proxy statements were materially false and misleading.

77. The misrepresentations and omissions in the proxy statements were material. The proxy statements were an essential link in the Director Defendants’ re-election to their directors’ positions (2008 and 2009 Proxy Statements), the amendments to the 2004 Equity Incentive Program (2008 and 2009 Proxy Statements), the amendment to the 2007 Director Equity Plan (2008 Proxy Statement), and the approval of the 2009 Employee Stock Purchase Plan (2009 Proxy Statement).

78. The Company was damaged as a result of the material misrepresentations and omissions in the 2008 and 2009 Proxy Statements, as alleged herein.

## **COUNT II**

### **AGAINST THE INDIVIDUAL DEFENDANTS FOR BREACH OF FIDUCIARY DUTIES OF LOYALTY AND GOOD FAITH**

79. Plaintiffs incorporate by reference all preceding and subsequent paragraphs as if fully set forth herein.

80. Individual Defendants, by reason of their positions as fiduciaries of the Company, owed to the Company the duties of undivided loyalty, good faith, and truthful disclosure.

81. As alleged herein, Individual Defendants breached their fiduciary duties of loyalty and good faith by knowingly causing the Company to: (1) falsely portray that its manufacturing facilities were compliant with FDA standards; (2) conceal the manufacturing deficiencies previously flagged by FDA inspectors; (3) conceal the true reason for the Company's inability to meet demand for its products; (4) materially mislead the Company's shareholders about the expected product and revenue growth of Cerezyme, Fabrazyme, and Myozyme; (5) materially mislead the Company's shareholders about the approval schedule of Lumizyme; (6) conceal from shareholders that the Company lacked adequate internal controls; and (7) fail to take appropriate action to prevent or correct this misconduct.

82. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary duties, Genzyme sustained damages, as alleged herein.

### **COUNT III**

#### **AGAINST INSIDER SALES DEFENDANTS FOR BREACHES OF FIDUCIARY DUTIES OF LOYALTY AND GOOD FAITH IN CONNECTION WITH INSIDER STOCK SALES**

83. Plaintiffs incorporate by reference and reallege each and every allegation set forth above, as though fully set forth herein.

84. At the time of each of the stock sales set forth herein, the Inside Sales Defendants knew, but did not disclose publicly, material non-public information regarding the contamination and manufacturing issues at the Company's Allston Facility. The Insider Sales Defendants made each of the stock sales described herein on the basis of and because of their knowledge of the material non-public information described herein.

85. At the time of their stock sales, the Insider Sales Defendants knew that when the material non-public information regarding contamination and manufacturing issues at the Company's Allston Facility was disclosed, the price of the Company's common stock would decrease. The Insider Sales Defendants' sales of their personally held Genzyme stock, based on their knowledge of this material non-public information, was a breach of their fiduciary duties of loyalty and good faith.

86. Since the use of the Company's proprietary information for their own gain constitutes a breach of the Insider Sales Defendants' fiduciary duties, the Company is entitled to the imposition of a constructive trust on any proceeds the Insider Sales Defendants obtained thereby.

#### **COUNT IV**

#### **AGAINST THE INSIDER SALES DEFENDANTS FOR UNJUST ENRICHMENT IN CONNECTION WITH INSIDER STOCK SALES**

87. Plaintiffs incorporate by reference all preceding and subsequent paragraphs as if fully set forth herein.

88. The Insider Sales Defendants were unjustly enriched by their receipt of proceeds from their illegal sales of Genzyme common stock, as alleged herein, and it would be inequitable to allow them to retain the benefits of their illegal conduct.

89. To remedy the Insider Sales Defendants' unjust enrichment, the Court should order them to disgorge to the Company all proceeds derived from their illegal sales of Genzyme common stock.

90. As a direct and proximate result of the Individual Defendants' foregoing breaches of fiduciary duties, the Company has sustained damages.

WHEREFORE, Plaintiffs demand judgment as follows:

- A. Against all of the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties;
- B. Imposing a constructive trust in favor of the Company for the amount of proceeds the Insider Sales Defendants received from their sales of Genzyme common stock alleged herein, in addition to all proceeds otherwise derived from their service as directors and/or executives of the Company;
- C. Ordering the Insider Sales Defendants to disgorge to the Company all proceeds derived from their sales of Genzyme common stock alleged herein, in addition to all proceeds otherwise derived from their service as directors and/or executives of the Company;
- D. Ordering appropriate equitable relief to remedy Defendants' misconduct;
- E. Awarding to Plaintiffs the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
- F. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiffs demand a trial by jury.

Dated: December 22, 2009

Respectfully submitted,

**GILMAN AND PASTOR, LLP**

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